

Assurance that these requirements will be satisfied is further provided by the enclosed Declaration attached hereto as Exhibit B.

B. The Rejection Under 35 U.S.C. 102(a) On the Kennett Abstract

Applicants respectfully traverse the rejection on Kennett.

Attached hereto as Exhibit C is a photocopy of the Terminal Progress Report relating to the work of Dr. Kennett of which the subject reference is an abstract. This report is publicly available and was obtained by Applicants' Attorney to determine precisely what Dr. Kennett has done.

A careful examination of this report indicates that it does not even render the subject claim obvious, let alone anticipated. No hybridoma was prepared and reported by Dr. Kennett which in any way suggests the subject hybridoma (which produce complement-fixing antibody against an antigen found on essentially all normal human peripheral T cells).

The Examiner's attention is respectfully directed to Tables 1 and 3 and to the three pages of description. As can be seen from the introductory paragraph, the entire purpose of Kennett's work was to determine whether monoclonal antibodies could be produced against human tumor associated antigens. The Examiner should appreciate that such monoclonal antibodies have no necessary connection to antibodies against antigens found on normal human cells. Accordingly, it is respectfully requested that this rejection be withdrawn.

C. Rejection of Claim 22 Under 35 U.S.C. 112 (second paragraph)

The term "mouse monoclonal antibody" is intended to cover monoclonal antibody produced from fused mouse cells

(as opposed to fused rat cells, fused human cells, etc.). As described in the specification, the claimed antibody is produced by a hybridoma formed by fusing cells from a mouse myeloma line and mouse spleen cells. It is believed that this term is clear from the specification and is readily understood by one skilled in the art.

In fact, the Examiner herself has used this term properly in the outstanding Official Action in Applicants' copending application Serial No. 33,639 and thus appears to readily understand what the term means. It is therefore respectfully requested that this rejection be withdrawn.

D. Rejection of Claims 1-3 and 22 Under 35 U.S.C. 112 (first paragraph)

It is respectfully submitted that the rejected claims read on a definite class of antibodies produced by fusion of cells from a mouse myeloma line and mouse spleen cells, which class of antibodies has a clearly defined and readily ascertainable set of characteristics.

These claims certainly do not cover "any T cell antibody now known or as may be developed in the future by any means", as asserted by the Examiner. On the contrary, these claims are specific to monoclonal antibodies produced by fusion of mouse cells, which antibody is complement-fixing and reacts with essentially all normal human peripheral T cells, but not with normal human peripheral B cells, null cells, or macrophages. Only antibodies which meet the limitations of the claims are covered thereby.

The limitations of the claims are completely commensurate with the disclosure of the specification. That

is, the disclosure teaches one skilled in the art how to make and use the claimed antibody as required by the first paragraph of Section 112. It is respectfully submitted that nothing more is required.

Because of these limitations in the claims, the claimed antibody differs significantly in kind from "all antibodies to T cells". First, the claimed antibody is monoclonal and hence is completely different from conventionally-produced antisera. Second, the claimed antibody is complement-fixing and is specific to an antigen on essentially all normal human peripheral T cells. This specificity had not existed previous to Applicants' invention and represents a significant advance in the art. These differences and distinguishing features are extensively discussed at pages 1 through 5 of the specification, to which the Examiner is respectfully referred.

E. The Objection to Insufficient Exemplary Matter

The Examiner has objected to the specification as containing insufficient exemplary matter to support the present antibody claims. Nevertheless, she has not rejected any claims on this ground, nor has she referred to any portion of the Patent Statute as a basis for this objection.

Applicants assert, on the contrary, that the specification as a whole enables the making and using of the claimed antibody as required by the Patent Laws and most particularly by 35 U.S.C. 112 (first paragraph). Applicants have taught one skilled in the art how to prepare monoclonal antibody having the characteristics set out in the claims. They are therefore entitled to claims of scope commensurate

with the scope of the description and need not be restricted to the narrowest claims which they have presented.

Certainly, Applicants are entitled to product claims referring specifically to monoclonal antibody produced from the deposited hybridoma (as set forth in newly-presented Claims 27 and 28). However, the enabling disclosure of the specification is considerably broader than this and fully supports Claims 1-3 and 22, as well as newly-presented Claims 27-31.

That Applicants have presented only one example of the preparation of the claimed monoclonal antibody is irrelevant to the enablement of the specification as a whole. The operative consideration is not the number of examples but rather whether one skilled in the art could follow the disclosure of the specification to produce the claimed antibody. Since one skilled in the art could so do, the claims should be allowed.

If the Examiner has any specific evidence or reason why she doubts the enablement of the pending claims by the specification, she is respectfully requested to make it of record.

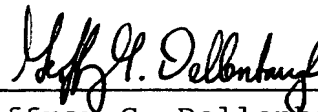
F. Double Patenting

While Applicants believe that the subject claims are indeed patentable over the claims of copending application Serial No. 22,132, they nevertheless enclose a terminal disclaimer in the interest of promoting the prosecution of the subject application. It is believed that this terminal disclaimer overcomes the rejection on double patenting.

G. Conclusion

For the reasons set out above, it is respectfully requested that all of the outstanding rejections be withdrawn and that the pending claims (1-3, 15-18, and 22-31) be allowed.

Respectfully submitted,



Geoffrey G. Dellenbaugh
Attorney for Applicants
Registration No. 26,864

GGD/dls
July 1, 1981

501 George Street
New Brunswick, N.J. 08903
(201) 524-9324

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D. C.

20231, on July 1, 1981

(Date of Deposit)

Geoffrey G. Dellenbaugh

Name of applicant, assignee, or
Registered Representative



(Signature)

July 1, 1981

(Date of Signature)